Food and Drug Administration

[Docket No. 96N–0222]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by October 10, 1996.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., rm. 10235, 725 17th St. NW., Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance: §§ 70.25 *Labeling requirements for color additives (other than hair dyes)* (21 CFR 70.25) and 71.1 *Petitions* (21 CFR 71.1) (OMB Control Number 0910–0185—Reinstatement).

Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or unless the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is approved already. Section 71.1 specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use.

FDA scientific personnel review color additive petitions to ensure that the intended use of the color additive in or on food, drugs, cosmetics, and medical devices is suitable and safe. Color additive petitions were specifically provided for by Congress when it enacted the Color Additive Amendments of 1960 (Pub. L. 94–295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, the number of new color additives approved would decrease.

FDA's color additive labeling requirements in § 70.25 require that color additives that are to be used in foods, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA estimates the burden of complying with the information collection provisions of the agency's color additive regulations as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
70.25	2	1	2			
71.1	2	1	2	1,700	3,415	$6,000
Total	2				3,415	$6,000

There are no capital costs associated with this collection.

This estimate is based on the number of new color additive petitions received in 1994. Although the burden varies with the type of petition submitted, a color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself. Because labeling requirements under § 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for number respondents is the same for § 70.25 as for § 71.1, and the burden hours for labeling are included in the estimate for § 71.1.

Dated: September 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–23098 Filed 9–9–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Alternative Medicine Program Advisory Council; Notice of Meeting

Pursuant to sec. 10(d) of the Federal Advisory Committee Act (FACA), as amended (Title 5, U.S.C. Appendix 2), notice is hereby given of the meeting of the Alternative Medicine Program Advisory Council on September 16, 1996 from 8:30 am to 5 pm and on September 17 from 8:30 am to 1 pm in the Versailles II Room of the Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland.

The entire meeting will be open to the public. The purpose of the meeting will be to update the Council on the progress of the Office of Alternative Medicine and obtain Council's advice on strategic planning for complementary and alternative medicine research. There will also be a scientific presentation, ''Shifting Paradigms in Growth Factor/Cytokine Biotechnology: The Science, the Paradigm, the Interface,'' by Barbara Brewitt, M.Div., Ph.D., Chief Scientist, Biomed Comm, Inc. and Leana Standish, N.D., Ph.D., Research Director, CAM Research Center, Bastyr University. Attendance by the public will be limited to space available.

Ms. Elizabeth Clay, Committee Management Officer, Office of Alternative Medicine, NIH, 9000 Rockville Pike, Building 31, Room 5B37, MSC 2182 Bethesda, MD 20892, phone (301) 594–1990, fax (301) 402–4741, E-Mail: bethclay@helix.nih.gov, will furnish the meeting agenda, roster of committee members, and substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Clay at the above location no later than September 11, 1996.

This notice is being published less than 15 days prior to the meeting due